

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of therapeutic regime of magnesium sulfate for 12-hours and 24-hours in postpartum severe preeclampsia

Protocol summary

Study aim

Comparison of the effect of two treatments with magnesium sulfate in preeclampsia

Design

Clinical trial, with parallel, randomized groups, phase 3 on 120 patients with quadruple blockade that was analyzed with Spss software version 24.

Settings and conduct

In this study, 120 mothers with preeclampsia referred to the gynecology and obstetrics ward of Besat Hospital in Sanandaj are evaluated. These individuals are randomly divided into 12-hour intervention group and 24-hour control group treated with magnesium sulfate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preeclampsia, 140/90 mm Hg or higher after 20 weeks of gestation, proteinuria with a plus or more Conditions for not entering: Eclampsia, HELLP syndrome

Intervention groups

Patients with preeclampsia are randomly divided into intervention group (12-hour sulfate therapy regimen) and control group (24-hour sulfate therapy regimen).

Main outcome variables

Systolic blood pressure before intervention Diastolic blood pressure before intervention Systolic blood pressure after intervention Diastolic blood pressure after intervention Time to start breastfeeding Time to start oral feeding Foley catheter insertion time Bedtime Ability to breastfeed Need to re-administer magnesium sulfate Incidence of eclampsia Side effects of magnesium sulfate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200503047287N1**

Registration date: **2020-09-02, 1399/06/12**

Registration timing: **prospective**

Last update: **2020-09-02, 1399/06/12**

Update count: **0**

Registration date

2020-09-02, 1399/06/12

Registrant information

Name

Fatemeh Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2245 0264

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic regime of magnesium sulfate for 12-hours and 24-hours in postpartum severe preeclampsia

Public title

Comparison treatment of magnesium sulfate for 12-hours and 24-hours in preeclampsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Preeclampsia Blood pressure 140/90 mm Hg or higher after 20 weeks of gestation Proteinuria with a rate of one plus or more

Exclusion criteria:
Eclampsia HELLP Syndrome

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of individuals to intervention and control groups by quadruple randomization block method: Pregnant mothers with preeclampsia referred to the obstetrics and gynecology ward of Besat Hospital Random assignment of individuals to the intervention and control group: Patients with preeclampsia randomly divided into the intervention group (12 hours) or the control group (24 hours) as follows: Patients are divided into two groups by forming four random blocks: group A (treatment with magnesium sulfate for 24 hours), group B (treatment with magnesium sulfate for 12 hours)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2020-04-27, 1399/02/08

Ethics committee reference number

IR.MUK.REC.1399.016

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

High blood pressure

Timepoint

Hospitalization time and every one hour during magnesium sulfate treatment

Method of measurement

The patient's systolic and diastolic blood pressure is measured every hour by a standard sphygmomanometer.

Secondary outcomes

1

Description

Incidence of seizures: Incidence of involuntary repetitive movements, Complications of magnesium sulfate: which is assessed by spinal reflexes through the patellar reflex, assessment of the number of breaths per minute and the amount of urine collected in the urinbag

Timepoint

Urine output is measured every hour with a Foley catheter

Method of measurement

Using a Foley catheter

Intervention groups

1

Description

Control group: Group A is a control group that includes pregnant mothers with preeclampsia referred to the obstetrics and gynecology ward of Besat Hospital who are being treated with 24-hour magnesium sulfate.

Category

Treatment - Drugs

2

Description

Intervention group: Group B is an intervention group that includes pregnant mothers with preeclampsia referred to the obstetrics and gynecology ward of Besat Hospital who are being treated with 12-hour magnesium sulfate.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Educational Hospital

Full name of responsible person

Nasrin Soofizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Farzin Rezaei

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact
Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Fatemeh Farahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

At the request of the journal that publishes the article, the data will be provided to the journal.

When the data will become available and for how long

At the time of publication of the article up to six months later

To whom data/document is available

Editor of the journal and academic researchers with the permission of the responsible author

Under which criteria data/document could be used

Only allowed to perform meta-analysis on data.

From where data/document is obtainable

By contacting the responsible author at amirh.brdrn@gmail.com

What processes are involved for a request to access data/document

The application should be sent to the e-mail of the responsible author by sending a resume and the purpose of achieving the research. After reviewing the application, information will be provided to them within a week.

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